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ARGUMENTS/REMARKS

After amendment, the pending claims are 1-7, 25, and 27-40. Claims 8-11 and 14 are canceled, without prejudice. Claims 37-40, which are free from the §103 and double patenting rejections, are rewritten in independent form and amended to overcome the §112 rejection, as suggested by the Examiner. Independent claims 1 and 28 are amended, without prejudice, to delete reference to the compounds of formula I. Applicants reserve the right to prosecute the subject matter deleted from the claims in a continuation application filed during the pendency of this application.

The remaining amended claims were amended to place the application in condition for allowance. Support for the claim amendments is found throughout the originally filed specification and claims and specifically on page 33, lines 26-30; page 35, lines 13-16; page 35, lines 17-19; and page 35, lines 23-25. No new matter is added by these amendments.

35 USC § 112, First Paragraph Rejection

Claims 35-40 are rejected under 35 USC § 112, first paragraph for reciting certain phases and time periods that are assertedly not presented in the originally filed specification.

Applicants respectfully request reconsideration and withdrawal of this rejection for the following reason.

Applicants assert that the pending claims are sufficiently described and enabled in the originally filed specification and claims as filed.

However, in an effort to place the application in condition for allowance, Applicants amended claims 35-40 to clarify the invention and to parallel the language in the specification at pages 34-36. Applicants note that these amendments do not narrow the scope of the invention. Support for these amendments to claims 35-40 are noted in the above paragraph.

Reconsideration of this rejection is requested.

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35 USC § 103(a) Rejection

Claims 1-11, 14, and 25-36 are rejected under 35 USC § 103(a) over International Patent Publication No. WO 00/66570 ('570), Applicants' acknowledgment on page 4, lines 3-5 in the present specification, and US Patent Application Publication No. 2002/0061875.

The Examiner asserted that the compounds of the rejected claims are generally provided for in '570, that Applicants admit that a progestin and estrogen can be administered concurrently, and Gast teaches administration of a placebo or pill free period for 7 days and discusses administration of the combination of agents for 21 days.

Applicants respectfully request reconsideration and withdrawal of this rejection for the following reasons.

Claims 8-11, 14, and 26 are canceled thereby rendering the outstanding rejection moot as applied to these claims.

While certain compounds of the present invention, as exemplified by the compound of formula II in claim 1, may be dominated by '570¹, "[t]he fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness".² No combination of '570, Gast, or the statement on page 4 of the present application suggests the selection of the compounds of formula II and the use thereof in combination with selective estrogen receptor modulators (SERM) as encompassed by claim 1, and the claims depending therefrom, of Applicants' invention. Absent this suggestion in the art, only the improper use of hindsight can explain this rejection. In fact, the inventors found that the compounds exemplified by compounds of formula II have unexpected potency.

As the Examiner is also aware, there must be a reasonable expectation of success that the claimed invention would work for its intended purpose. That expectation is lacking in the combination of '570, Gast, and Applicants' statement on page 4. In fact, one would not have reasonably selected the compound of formula II from '570 with the

¹ On page 6, lines 16-17 of the Office Action dated April 1, 2005

² In re Baird, 29 USPQ2d 1550, (Fed. Cir. 1994)

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expectation of its having unexpected potency. That motivation is only provided by the teachings of Applicants' specification.

No combination of '570, Gast, and Applicants' statement on page 4 of the present application suggests the present invention.

Reconsideration of this rejection is requested.

Double Patenting Rejection

Claims 1-11, 14, and 25-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 91 and 92, and the claims depending therefrom, of US Patent No. 6,436,929 in view of '570 and Gast.

Applicants respectfully request reconsideration and withdrawal of this rejection for the following reason.

As the Examiner is aware, in determining whether a nonstatutory basis exists for a double patenting rejection, it is to be determined if any *claim* in the application, i.e., the present application, defines an invention that is merely an obvious variation of an invention claimed in the patent, i.e., claims 91 and 92 of '929. Claim 91 of '929 is a broad claim drawn to methods of contraception and claim 92 is drawn to pharmaceutical compositions. Claims 91 and 92 refer to compounds whereby Q¹ is NR⁷ or CR⁸R⁹, but not S as provided by the claims of Applicants' invention. Therefore, on that point alone, '929 in combination with '570 and Gast does not teach or suggest compounds whereby Q¹ is S, which compounds are provided by Applicants' invention.

Further, MPEP § 804 provides that "[d]omination and double patenting should not be confused". Applicants agree that claim 91 of '929 provides a method of contraception using compounds that are a broad genus of the compounds encompassed by the claims of the present application with respect to the R¹-R⁵ substituents. However, the compounds of claim 91 of '929 are also a species of the compounds encompassed by the claims of the present application with respect to Q¹.

In order for one to select the compounds encompassed by formula II of Applicants' claims, one would need to be motivated to select (i) not only a pyrrole, but a

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2-cyanopyrrole at the 6-position whereby the N-atom is alkylated; (ii) a S-atom at the 2-position; (iii) a H-atom at the 1-position; and (iv) H-atoms at the 5-, 7-, 8-, and 9-positions to provide the compounds of formula II claimed by Applicants. There is no motivation in '929, '570, or Gast to select the specifically claimed compounds of formula II and then combine the same with selective estrogen receptor modulators. That motivation is ONLY provided by Applicants' specification.


Further, claim 92 of '929 only provides a pharmaceutical composition. This claim provides no motivation alone, or in combination with any of the secondary documents, to select the specifically claimed compound of formula II and combine the same with selective estrogen receptor modulators for the use in contraception. That motivation is ONLY provided by Applicants' specification.

In view thereof, this double patenting rejection may properly be withdrawn.
Reconsideration of this rejection is requested.

The Director is hereby authorized to charge the extension fee of \$120.00, as well as any deficiency in any fees due with the filing of this paper or during the pendency of this application, or credit any overpayment in any fees to our Deposit Account Number 08-3040.

Respectfully submitted,

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